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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,507	10/14/2003	Bernard Andreas	021629-001900US	3531

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EXAMINER	
OU, JING RUI	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,507	ANDREAS ET AL.	
	Examiner	Art Unit	
	Jing Rui Ou	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *4,14,and 21-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-13, and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/05/2005 and 02/09/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the non-provisional application filed on October 14, 2003. Claims 1-34 are pending. Claims 1, 11, 21 and 27 are independent. Claims 4, 14, and 21-34 are withdrawn from consideration.

Election/Restrictions

2. Applicant's election without traverse of claims 1-3, 5-13, and 15-20 in the reply filed on 10/08/2007is acknowledged.

Specification

3. The disclosure is objected to because of the following informalities: a) In line 9 of page 7, "and" should be inserted between "withdrawn" and "part." b) In line 23 of page 9, "25b" should be "25a." c) In line 7 of page 2, line 2 of page 3, line18 of page 9, and line 12 of page 13, the status of US Pat. Application No.: 10/412,714 (now US Pat. No: 7,137,993 B2) should be updated to US Pat. No: 7,137,993 B2. In the specification, "stent pushing member" should be "stent-pushing member" in line 31 of page 4, line 22 of page 5, line 15 of page 7, line 29 of page 9, lines 4-5 of page 13, line 18 of page 13, and line 3 of page 14.

Appropriate correction is required.

Claim Objections

4. Claims 9, 11, and 20 are objected to because of the following informalities: In claims 9, 11, and 20, "stent pushing member" should be "stent-pushing member." Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-2, and 5-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 22 of U.S. Patent No. 7,192,440 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3 and 22 in U.S. Patent No. 7,192,440 B2 disclose all the limitations of the instant claims.

7. Claim 3 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,192,440 B2 in view of Shaknovich (US Pat. No.: 5,807,398). Claims 1-3 of patent No. 7,192,440 B2 discloses all the limitations of the claim but fails to disclose the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member. However,

Shaknovich explicitly discloses a shuttle (1, Fig. 1) that is fixedly disposed over at least part of the catheter shaft (7, Fig. 1) and the expandable member (8, Figs 1 and 4 and Col. 4, lines 22-31). The motivation/suggestion for doing so would have been to be advanced into a patient as a shuttle-balloon catheter assembly (Col. 11, lines 1-16). Therefore, it would have been obvious to combine Shaknovich with claims 1-3 of patent No. 7,192,440 B2 to obtain the invention as specified in the instant claim.

8. Claims 9-12 and 15-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7 of U.S. Patent No. 7,192,440 B2 in view of Chermoni (US Pat. No.: 7,147,655 B2) and Acosta et al (US Pat. No.: 7,147,655 B2). U.S. Patent No. 7,192,440 B2 discloses all the limitations of the instant claims except for the stent segments that are slidably disposed along the shuttle, stent pushing member disposed over the shuttle, an abutment at or near a distal end of the shuttle, and a valve member coupled with the sheath.

However, Acosta et al explicitly discloses stent segments (182, Fig. 44) that are slidably disposed along the shuttle and a stent-pushing member (394, Fig. 44) disposed over the shuttle, proximal to the plurality of stent segments, for advancing the stent segments along the shuttle in a direction from proximal to distal. In addition, Acosta et al explicitly discloses at least one valve member (185, Fig. 44) coupled with the sheath (184, Fig. 44) for selectively retaining at least one stent segment within the sheath. The motivation/suggestion for having slidable stent segments and a stent-pushing member is to axially advance each stent by pushing on the proximal end of the proximal-most stent (Col. 14, lines 42-44). The motivation/suggestion for having at least one valve

member is to facilitate selective deployment of one or more stents at a target site (Col. 17, lines 1-3).

Furthermore, Chermoni teaches an abutment (barrier, next to 610a, Fig. 7) at or near a distal end of the shuttle (carriage, 605, Fig. 7) for preventing the plurality of stent segments from being advanced beyond the distal end of the shuttle. It is obvious that the motivation/suggestion for doing so would have been to block the stents from sliding beyond the shuttle.

Therefore, it would have been obvious to combine Chermoni and Acosta with Patent No. 7,192,440 B2 to obtain the invention as specified in the instant claims.

Claim Rejections - 35 USC § 103

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-2, 5-12, 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Acosta et al (US Pat. No.: 7,137,993, B2).

In regard to claim 1-2, 5-12, 15-20 Chermoni discloses:

A) a stent delivery device for delivering a plurality of stent segments to a treatment site, the device comprising: a catheter shaft (124, Fig. 1) having a proximal end and a distal end; an expandable member (balloon, 104, Fig. 7) coupled with the catheter shaft near the distal end; a shuttle (carriage, 605, Fig. 7) disposed coaxially over at least part of the catheter shaft and the expandable member, at least part of the shuttle being radially expandable (Para. [0042]); and a plurality of stent segments (206a, 206b, 206c, Fig. 7) disposed along the shuttle;

B) the shuttle is slidably disposed over at least part of the catheter shaft and the expandable member (Para. [0041]);

C) the stent segments are fixed to the shuttle until they are expanded into a deployed position (Paras.[0041]-[0042]);

D) the shuttle further comprises an abutment (barrier, next to 610a, Fig. 7) at or near a distal end of the shuttle for preventing the plurality of stent segments from being advanced beyond the distal end of the shuttle;

E) at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

Chermoni does not appear to discloses:

A) an axially movable sheath disposed over at least part of the catheter shaft and the expandable member and moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand, thus causing at least one of the plurality of stent segments to expand;

B) sheath is disposed over the shuttle;

C) sheath is adapted to expose a first portion of the expandable member to deploy a first selected number of stent segments;

D) the sheath is adapted to further expose at least a second portion of the expandable member to deploy a second selected number of stent segments.

E) the stent segments are slidable, the device further comprising a stent-pushing member, proximal to the plurality of stent segments, for advancing the stent segments along the shuttle in a direction from proximal to distal.

However, Acosta et al explicitly discloses:

A) an axially movable sheath (184, Fig. 44) disposed over at least part of the catheter shaft (188, Figs. 13A and 44) and the expandable member (190, Fig. 44) and moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand, thus causing at least one of the plurality of stent segments to expand (Col 16, lines 20-23).

B) the sheath is disposed over the shuttle (inner tube, 392, Fig. 44);

C) the sheath is adapted to expose a first portion of the expandable member to deploy a first selected number of stent segments (Col. 27, lines 53-62);

D) the sheath is adapted to further expose at least a second portion of the expandable member to deploy a second selected number of stent segments (Col. 27, lines 62-67);

E) the stent segments (182, Fig. 45A) are slidably disposed along the shuttle (375, Fig. 45A), the device further comprising a stent-pushing member (outer tube, 394, Fig. 44) disposed over the shuttle, proximal to the plurality of stent segments, for advancing the stent segments along the shuttle in a direction from proximal to distal (Fig. 44).

Chermoni and Acosta et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni and Acosta et al before him or her, to modify the stent delivery device of Chermoni to include an axially movable sheath of Acosta et al.

The suggestion/motivation for having such a sheath would have been to prevent the expansion of the remaining proximal portion of the balloon and keep the remaining stents to be unexpanded within the sheath (Col. 16, lines 35-38). The motivation/suggestion for having slidable stent segments and a stent-pushing member

is to axially advance each stent by pushing on the proximal end of the proximal-most stent (Col. 14, lines 42-44).

Therefore, it would have been obvious to combine Acosta et al with Chermoni to obtain the invention as specified in the instant claims.

12. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Acosta et al (US Pat. No.: 7,137,993, B2) as applied to claims 1 and 11 above, and further in view of Shaknovich (US Pat. No.: 5,807,398).

In regard to claims 3 and 13, Chermoni and Acosta et al disclose all the limitations of the claim as taught above but fail to disclose that the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member.

However, Shaknovich explicitly discloses a shuttle (1, Fig. 1) that is fixedly disposed over at least part of the catheter shaft (7, Fig. 1) and the expandable member (8, Figs 1 and 4 and Col. 4, lines 22-31).

Chermoni, Acosta et al, and Shaknovich are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Chermoni, Acosta et al, and Shaknovich before him or her to modify the stent delivery device of Chermoni and Acosta et al to include a shuttle that is fixedly disposed over at least part of the catheter shaft and the expandable member of Shaknovich.

The motivation/suggestion for doing so would have been to be advanced into a patient as a shuttle-balloon catheter assembly (Shaknovich, Col. 11, lines 1-16).

Therefore, it would have been obvious to combine Shaknovich with Acosta et al and Chermoni to obtain the invention as specified in the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jing Rui Ou whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571)272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

JOSEPH DEL SOLE
SUPERVISORY PATENT EXAMINER
10/22/07